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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,455	08/22/2001	Matthew O' Keefe	449142000120	9593

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EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,455

Applicant(s)

O' KEEFE ET AL.

Examiner

William H. Beisner

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-- Th MAILING DATE of this communication appears on th cover sh t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3&6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 31-54, in Paper No. 12 is acknowledged.
2. Claims 1-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

Information Disclosure Statement

3. The information disclosure statements filed 24 Sept. 2001 and 26 Feb. 2002 have been considered and made of record.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 45 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 45, "the component" lacks antecedent basis. Claim 45 directly depends from claim 31 which is silent as to "a component" as a positively recited structure of the claimed

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device. Note claims 43 and 44 recite that the device further includes "a reaction component". It is suggested that claim 45 depend from claim 43 or 44 rather than claim 31.

In claim 49, "the component" lacks antecedent basis. Claim 49 directly depends from claim 47 which is silent as to "a component" as a positively recited structure of the claimed device. Note claim 48 recites that the device further includes "a reaction component". It is suggested that claim 49 depend from claim 48 rather than claim 47.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 31-36 and 43-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over deMacario et al.(US 4,682,890) in view of Garyantes (US 6,565,813 or WO 99/39829).

With respect to claim 31, the reference of deMacario et al. discloses an apparatus for containing multiple micro-volume liquid samples comprising a substrate (30), wherein the substrate defines a plurality of sample chambers (32-38), wherein each sample chamber: (a) extends through the substrate (30), (b) comprises one or more walls and an opening at each end, and (c) holds a sample such that the sample is in the form of a thin film such that a liquid sample present in one sample chamber does not intermix with a liquid sample present in another sample chamber (See column 7, lines 1-40).

While the reference of deMacario et al. discloses that substrate (30) can be made of a glass, plastic or quartz material (See column 7, line 32), the instant claims differ by reciting that the substrate is made of titanium.

The references of Garyantes disclose a device for holding multiple micro-volume liquid samples wherein the samples are held within the sample chambers by surface tension (See the abstract of both references). The reference of Garyantes additionally discloses that the sample holding substrate can be made from a number of known materials including titanium (See page 41, lines 1-7 of the PCT reference and column 26, lines 41-49, of the US Patent reference).

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In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ titanium as the substrate for the device disclosed by the reference of deMacario et al. for the known and expected result of providing an art recognized equivalent for supporting multiple micro-volume liquid samples. Use of corrosion resistant titanium would be advantageous over glass, plastic or quartz since it would not be as fragile as a glass, plastic or quartz substrate.

With respect to claim 32, the thickness of the substrate is less than the diameter of the sample holding opening in the substrate (See column 6, lines 45-48, and column 7, lines 9-12).

With respect to claims 33 and 38, the substrate includes hydrophobic regions (See column 7, lines 12-16).

With respect to claims 34-36, the substrate has upper and lower surfaces and the sample chambers have the shape of a right circular cylinder with an axis perpendicular to the faces of the substrate (See Figure 2).

With respect to claims 43 and 44, the reference of deMacario et al. discloses the use of pre-anchored reagents on the inner surfaces of circular openings (See column 10, lines 55-68).

With respect to claim 45, while the reference discloses that the device is capable of performing biochemical or biological reactions (See column 10, lines 55-58), the reference is silent as to performing nucleic acid reactions. However, nucleic acid reactions or assays are notoriously well known in the art a biochemical or biological reactions. As a result, it would have been obvious to one of ordinary skill in the art to employ the device of deMacario et al. to perform any know nucleic acid assay, such as for performing nucleic acid hybridizations and/or

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amplifications since the device is recognized in the art for simultaneous contact of a plurality of samples with assay reagents.

With respect to claims 46, it would have been obvious to one of ordinary skill in the art to clean and/or sterilize the device prior to use for the known and expected result of eliminating any contaminating material which could interfere with the amplification reaction and/or compromise the integrity of the assay.

With respect to claim 47, while the claim recites a "kit", the claim is structurally the same as that of claim 31 and therefore is obvious for the same reasons as set forth with respect to claim 31.

With respect to claim 48, the thickness of the substrate is less than the diameter of the sample holding opening in the substrate (See column 6, lines 45-48, and column 7, lines 9-12).

With respect to claim 49, while the reference discloses that the device is capable of performing biochemical or biological reactions (See column 10, lines 55-58), the reference is silent as to performing nucleic acid reactions. However, nucleic acid reactions or assays are notoriously well known in the art as biochemical or biological reactions. As a result, it would have been obvious to one of ordinary skill in the art to employ the device of deMacario et al. to perform any known nucleic acid assay, such as for performing nucleic acid hybridizations and/or amplifications since the device is recognized in the art for simultaneous contact of a plurality of samples with assay reagents.

With respect to claims 50 and 51, whether the device is manufactured with a hydrophobic substance or the substance is applied prior to use would have been merely an obvious matter in design choice while still providing the required hydrophobic coating on the substrate surfaces.

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With respect to claims 52-54, while the reference discloses the use of reagents and an environment for performing the assay, the reference is silent as to the packaging of these items as a kit. However, it would have been obvious to one of ordinary skill in the art to provide all of the components (i.e., the test device, the reagents, liquid transfer devices, and thermal cycling device) required to perform the device as a kit for the known and expected result of facilitating the performance of the assay by providing all required components for performing the assay.

10. Claims 31, 33-42, 46, 47 and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter (WO 99/34920) in view of Garyantes (US 6,565,813 or WO 99/39829).

With respect to claim 31, the reference of Hunter discloses an apparatus for containing multiple micro-volume liquid samples comprising a substrate (10), wherein the substrate defines a plurality of sample chambers (12), wherein each sample chamber: (a) extends through the substrate (10), (b) comprises one or more walls and an opening at each end, and (c) holds a sample such that the sample is in the form of a thin film such that a liquid sample present in one sample chamber does not intermix with a liquid sample present in another sample chamber (See column pages 4-6 and Figure 1).

While the reference of Hunter discloses that substrate (10) can be made of a glass, plastic, quartz material or metal (See page 6, lines 27-34), the instant claims differ by reciting that the substrate is made of titanium.

The references of Garyantes disclose a device for holding multiple micro-volume liquid samples wherein the samples are held within the sample chambers by surface tension (See the

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abstract of both references). The reference of Garyantes additionally discloses that the sample holding substrate can be made from a number of known materials including titanium (See page 41, lines 1-7 of the PCT reference and column 26, lines 41-49, of the US Patent reference).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ titanium as the substrate for the device disclosed by the reference of Hunter for the known and expected result of providing an art recognized equivalent for supporting multiple micro-volume liquid samples. Use of corrosion resistant titanium would be advantageous over glass, plastic or quartz since it would not be as fragile as a glass, plastic or quartz substrate.

With respect to claims 33 and 37-42, the substrate (10) is constructed of a hydrophilic core material (26,42) and the top and bottom surfaces include hydrophobic material, which forms hydrophobic annular rings along the wall of the chamber (28,40)(See Figure 5 which depicts two hydrophobic rings along the wall of the chamber and defines one non-hydrophobic ring therebetween.

With respect to claims 34-36, the substrate has upper and lower surfaces and the sample chambers have the shape of a right circular cylinder with an axis perpendicular to the faces of the substrate (See Figure 1). The substrate (10) includes through holes (12) that may be circular right cylinders or have rectangular cross-sections (See page 4).

With respect to claims 46, it would have been obvious to one of ordinary skill in the art to clean and/or sterilize the device prior to use for the known and expected result of eliminating any

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contaminating material which could interfere with the amplification reaction and/or compromise the integrity of the assay.

With respect to claim 47, while the claim recites a "kit", the claim is structurally the same as that of claim 31 and therefore is obvious for the same reasons as set forth with respect to claim 31.

With respect to claims 50 and 51, whether the device is manufactured with a hydrophobic substance or the substance is applied prior to use would have been merely an obvious matter in design choice while still providing the required hydrophobic coating on the substrate surfaces.

With respect to claims 52-54, while the reference discloses the use of reagents and an environment for performing the assay, the reference is silent as to the packaging of these items as a kit. However, it would have been obvious to one of ordinary skill in the art to provide all of the components (i.e., the test device, the reagents, liquid transfer devices, and thermal cycling device) required to perform the device as a kit for the known and expected result of facilitating the performance of the assay by providing all required components for performing the assay.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 31 and 43-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 29 of copending Application No. 09/789,601. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 31 and 43-46 are anticipated by claim 29 of application '601. Claim 29 of application '601 encompasses an apparatus that includes a titanium substrate with the same sample holding chambers, the device is substantially free of contaminating amplifiable polynucleotides and includes at least one reagent used for amplifiable polynucleotides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 31-54 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15, 16, 18-28 and 30-38 of copending Application No. 09/789,601 in view of Garyantes (US 6,565,813 or WO 99/39829).

Claims 15, 16, 18-28 and 30-38 encompass an apparatus and kit that is essentially the same as that instantly claimed in claims 31-54 of the instant application.

The instant claims differ by further reciting that the substrate is made of a titanium material.

The references of Garyantes disclose a device for holding multiple micro-volume liquid samples wherein the samples are held within the sample chambers by surface tension (See the

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abstract of both references). The reference of Garyantes additionally discloses that the sample holding substrate can be made from a number of known materials including titanium (See page 41, lines 1-7 of the PCT reference and column 26, lines 41-49, of the US Patent reference).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ titanium as the substrate for the device disclosed by the reference of Hunter for the known and expected result of providing an art recognized equivalent for supporting multiple micro-volume liquid samples. Use of corrosion resistant titanium would be advantageous over glass, plastic or quartz since it would not be as fragile as a glass, plastic or quartz substrate.

This is a provisional obviousness-type double patenting rejection.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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A handwritten signature in black ink, appearing to read 'William H. Beisner', with a long horizontal flourish extending to the right.

William H. Beisner

Primary Examiner

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WHB